Standard Operating Procedure – Retiring User Accounts for the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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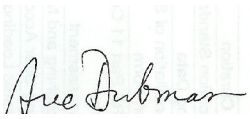
Department Approval:



Sue Dubman

NCICB Applications Director

QA Approval:

Brenda Duggan

Acting NCICB QA Officer

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for retiring user accounts for the NCICB clinical data management systems. This SOP is applicable when a user leaves the organization, or the user's role no longer requires access to data management system. Adherence to this SOP protects the security, privacy and data integrity of clinical data in the systems.

2. Scope

This SOP will be followed when retiring or inactivating user accounts and passwords that provide access to NCICB clinical data management systems applications. This SOP applies to all users of the NCICB clinical data management systems in the conduct of clinical trial research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 The Cancer Center's Site Coordinator must review and verify that all users with access to a specific study have the appropriate access privileges.

3.2 The Cancer Center's Site Coordinator must notify the NCICB Applications Support Database Administrator (DBA) that a user no longer requires access to a specific study or program, when: a) the user's employment status with the site is terminated or changes (such as a transfer); or, b) when the user's work activities no longer require access to the study or program.

3.3 When a user account is retired, the user is not released from any agreements regarding the confidentiality of patient data.

3.4 The Site Coordinator will also notify NCICB Applications Support when the study is completed and the data are to be frozen (or locked), or if the clinical study remains open but enrollment or capture of clinical trials data is infrequent. The NCICB Applications Support will then remove the access rights to any frozen or locked studies for all users with access to that study or limit access to 'read only' on studies that remain open and enrollment is infrequent. Approved users with access to other ongoing studies will retain those access rights for as long as is appropriate.

3.5 As provided for in the *SOP for Establishing and Maintaining User Accounts*, the NCICB will set and maintain user account standards (e.g. username and password requirements, account locks, expirations and retirements) in accordance with 21 CFR Part 11 and NCICB security requirements.

3.6 For accounts that have no activity for an extended period of time, NCICB will automatically restrict user access to 'read only', removing data entry or update privileges. (Note: This requirement is not currently in place but will be implemented in the future)

3.7 All caBIG™ sites will use this SOP for guidance on retiring user accounts in NCICB clinical data management systems.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	IT001	SOP for Establishing and Maintaining User Accounts
4.3	CV001	SOP for Complying with 21 CFR Part 11 for the caBIG™ Program
4.4	AD004	SOP for Information Security Compliance
4.5	AD005	SOP for Protecting Patient Privacy
4.6	N/A	Title 21 CFR Part 11

5. Roles & Responsibilities

Role	Responsibility
User	• Notify the Study Coordinator when their employment status changes, or their work responsibilities related to a specific study are completed or changed.
Site Coordinator	• Verify the level of access to the NCICB clinical data management system that a user has is appropriate to the level the user needs to perform his/her job function. • Verify the account and confirms the user acknowledges that they remain bound to confidentiality of patient data. • Communicate changes in user employment status, study team status or study completion status to NCICB Applications Support.
NCICB Applications Support	• Generate a Help Desk ticket to track requests to retire a user account or to limit access to 'read only' privilege when activity on the study is infrequent or when a study is locked and/or frozen for reporting requirements. • When a clinical research trial is locked or frozen at study completion and/or for reporting, remove all write access privileges to the study. • Deactivate the user account for users who do not require read access to the data for analysis and reporting requirements. • Review and clean up accounts that have not been active or used within the last 90 days.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Retiring User Accounts	This document provides the detailed steps to be followed in retiring a user account in the NCICB clinical data management systems.
2) Process Flow for Retiring User Accounts	This document visually depicts the activities, by role, to be followed in retiring user accounts in an NCICB application.